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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference NO 7188/WO | FOR FURTHER ACTION See Form PCT/PEA/416 | |
| International application No. PCT/EP2004/007092 | International filing date (day/month/year) 30.06.2004 | Priority date (day/month/year) 30.06.2003 |
| International Patent Classification (IPC) or national classification and IPC A61K35/20, A61K38/17, A61K38/16, A61K35/78, A23L1/305, A23L1/0524, A23L1/308, A61P3/10, A61P3/06 | | |
| Applicant NESTEC S.A. et al. | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 1 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | |
| Date of submission of the demand 19.01.2005 | Date of completion of this report 14.04.2005 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Pilling, S Telephone No. +49 89 2399-8461 | |



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/007092

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-11 as originally filed

Claims, Numbers

1-4 received on 10.02.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/007092

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-4 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-4 |
| Industrial applicability (IA) | Yes: Claims | 1-4 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The documents cited in the International Search Report (ISR) are consecutively numbered D1 to D12 in the order of their listing. If not indicated otherwise, reference is made to the passages cited in said ISR.
2. With regard, to the scope of the search, a preliminary search for the subject matter of originally filed Claim 1 revealed many documents potentially relevant in respect of lack of novelty and/or inventive step of this claim. So many documents were found that a full and meaningful search of the full scope of this claim was not possible. Even a more restricted search directed towards the preferred subject matter of originally filed Claims 2 to 4 revealed many further documents potentially relevant in respect of lack of novelty and/or inventive step of this claim. Thus, the present search report merely includes a sample of the many potentially relevant documents found. A further search may be required, if and when the scope of the present claims is delimited from the presently available prior art documents. The Applicant is also warned that any delimited claims should comply with the requirements of Article 6 PCT (conciseness) and Rule 13.1/13.2 PCT (unity of invention). Further consideration will be given to this matter at the appropriate time.
3. The subject matter of Claims 1 to 4 lack novelty in view of the following prior art disclosures; these disclosures all appear to essentially involve the treatment of insulin resistance (note this is merely a mode of action) as presently claimed;

D1 and D2 disclose a nutrition intervention composition for providing glycaemic control in Type II diabetics (see paragraph 0028 in D1 and paragraphs 0036 and 0037 in D2) comprising psyllium or pectin (see paragraph 0059 in D1 and 0062 in D2) and other fibres.

D3 discloses a composition comprising a milk protein hydrolysate further comprising acetogenic fibres such as soy, pea, pectin, guar, gum arabic and fructooligosaccharide (see paragraph 0054) for the treatment of diabetes and

Syndrome X (see paragraph 0015)

D4 discloses the favourable therapeutic effects of soya and cellulose fibres of post prandial glycaemia in Type II diabetic patients (see the conclusions)

D5 discloses guar-carob for the treatment of post prandial glycaemia in Type II diabetic patients (see the summary and the first paragraph of "Metodica dello studio" on page 498)

D6 discloses the use of locust bean gum to decrease the glycaemic index in Type II diabetic patients (see the abstract)

D7 discloses that psyllium improves glycaemic control in men with type II diabetes and hypercholesterolaemia (see the abstract)

D9 discloses the use of guar gum (see column 1 lines 6 to 9) for improving glucose tolerance and reducing insulin requirements in Type II diabetics

D11 discloses a composition comprising pectin for reducing post prandial blood sugar levels in patients with Type II diabetes (see paragraph 0027 and Figure 3)

D12 reports an improvement in insulin sensitivity in patients treated with guar (see abstract)

4. Thus, the subject matter of Claim 1 to 4 is not new in view of the disclosures of each of the documents listed herein above (Article 33(2) PCT).
5. It may also be helpful to note that even in the event that novelty could be established, *e.g.* by restricting the claims to particular acetogenic fibres not mentioned in the prior art, that it appears unlikely that such amended claims would fulfil the requirements of Article 33(3) PCT with respect to inventive step. In this regard, the use of dietary fibre in general to treat diabetes and dyslipidaemia appears to be well documented.

Re Item VIII

Certain observations on the international application

6. Present Claim 1 is directed towards the preparation of a composition "*for treating, preventing and/or improving insulin resistance*". Dependent Claim 4 is however directed towards "*preventing dylipidaemia*". Thus, the subject matter of dependent Claim 4 is not consistent with the subject matter of present Claim 1 and casts doubt on the scope of the claims (Article 6 PCT).

17.11.04

Claims

1. Use of a composition comprising acetogenic fibres for the preparation of a nutritional and/or a pharmaceutical composition for treating, preventing and/or improving insulin resistance.
2. The use according to claim 1, wherein the acetogenic fibre is lactulose, citrus pectin, apple pectin, carrot pectin, soybean fibre, soy fibre, acacia gum, gum Arabic or a mixture thereof.
3. The use according to claim 1 or 2, wherein the amount of acetogenic fibres in the composition is in the range of from 0.2 to 90 % by weight, preferably from 0.5 to 50 % by weight, more preferably 0.7 to 30 % by weight, even more preferably 5 to 25 % by weight, most preferred about 7 % by weight, based on the total weight of the composition.
4. The use according to any preceding claim, for increasing insulin sensitivity and/or preventing dyslipidemia.
5. A method for treating, preventing and/or improving insulin resistance which comprises administering an effective amount of a composition comprising acetogenic fibres.
6. The method of claim 5 wherein the acetogenic fibres are administered in an amount of from 0.1 to 1.5g per kg body weight, preferably from 0.3 to 0.8g per kg body weight, more preferably 0.5 g per kg body weight

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